UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,115	12/26/2001	Steve Qi	033236-0115	9673

7590 10/21/2004

Stephen A Bent
Foley & Lardner
Washington Harbour
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,115	QI ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5* is/are allowed.

6)☒ Claim(s) *6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks filed 7/20/04 are acknowledged, entered and considered. In view of Applicant's request claims 1-13 have been amended. Claims 1-13 are now pending in the application. The objection to the title, specification and claims, and the rejections under 35 U.S.C. 101, 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) over the prior art of record are withdrawn in view of Applicant's amendment, remarks filed 7/20/04. However, the rejection under 35 U.S.C. 112, first paragraph for claims 6-13 is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-13 as currently amended remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing a pharmaceutical formulation for the release of a peptide or a salt thereof comprising the peptide of SEQ ID NOS:7 and 6 with pharmaceutically acceptable polymer as recited in

claims 1-5, does not reasonably provide methods for the treatment of a human pathology by administering the claimed pharmaceutical formulation (claim 6) or for treatment or protection against disorder of bone growth (claim 7), for a method of preparing a controlled release medicament for the treatment or protection against a disorder of bone growth comprising the peptide of SEQ ID NO:7 (claims 8 and 9) wherein the disorder are those recited in claims 10-13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 7/20/04 have been fully considered but they are not persuasive. Applicant's arguments that claims 6-13 as amended, are drawn to methods and a pharmaceutical formulations for treating or protecting against disorders of bone growth, to a methodology for preparing a controlled release medicament for these purposes, and to a methodology for treating bone-growth disorders. Thus, the pharmaceutical formulations, the methods of preparing a controlled release medicament, and the methods of treatment are fully and clearly enabled by the present specification as originally filed, and as such, the requirements of the first paragraph of 35 U.S.C. 112, have been met is not persuasive.

Contrary to Applicant's arguments, the specification does not adequately teach a formulation which is useful in the treatment of human pathologies such as disorders of bone growth (including age-related osteoporosis and osteoporosis associated with post-menopausal hormone status, primary and secondary hyperparathyroidism, disuse osteoporosis, diabetes-related osteoporosis, and glucocorticoid-related osteoporosis) as

recited on page 3, last paragraph in instant specification and as presently claimed in claims 6-13; rather, the specification teaches the preparation, synthesis and microencapsulation of the peptides claimed as disclosed on pages 4-9, Examples 1 and 2, and Tables 1 and 2. Figure I show the effect of increasing doses of GnRH-II on serum calcium concentrations in ovariectomised rats. Examples 3 and 4 teach the analysis of the effects of GnRH-II and analogues on osteogenic cell population *in vitro*. Example 5 shows the expression analysis of GnRH mRNA in osteogenic and osteoclastic II population. Example 6 describes the effect of GnRH-II on bone mineral density in the ovariectomised rat and Example 7 discloses the cellular localization of GnRH-II in paraffin sections of normal rat bone and human bone. Thus, Examples 3-7demonstrate the biological activity of the peptides of interest as admittedly acknowledged on page 14, paragraph 5, lines 2-3 in the instant specification.

Therefore, the instant specification does not commensurate with the claimed subject matter in which the peptides tested for biological activity against GnRH-II *in* vitro is expected to be particularly useful in the treatment or protection of all kinds of human pathologies as disclosed above and claimed in claims 6-13. There is no evidence in the instant specification to use or administer the pharmaceutical formulation in therapeutically effective amount as claimed, except for the mere recitation of protocols on pages 2-4 and Examples 3-7 in the instant specification disclosing the preparation of the pharmaceutical formulation without appropriate dosages to be administered for the intended treatment or protection of diseases of the bone and prostates. Further, there are no sufficient data or evidence or working example(s) to substantiate such protocols

of using the pharmaceutical formulations of claims 1-5 in the methods and pharmaceutical formulations of claims 6-13 in the manner claimed. Hence, the only support of the claimed pharmaceutical formulation in the specification is Applicant's supposition of the invention as recited in the protocols. Further, Applicant's claims are directed to a variation of peptides by using specific therapeutically effective amount of pharmaceutical formulation, and there is no objective factual evidence in the specification showing that treatment or prevention has occurred using the specific therapeutically effective amount of pharmaceutical formulation claimed. Hence, one cannot administer specific effective amount of a pharmaceutical formulation in all situation without appropriate testing.

Thus, the claims are based on pure speculation that the method would be effective since Applicant has not established any *nexus* between an effective amount of the claimed peptides and its use in the manner claimed. Therefore, in view of the above, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Further, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of pharmaceutical formulation in a variety of peptides are contemplated and are encompassed as well as wide range of situations (i.e., various kinds of disorders). The results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed. Hence, one of ordinary skill in the art would not be able to identify all the pharmaceutical formulations with wide range of dosages (e.g., between 1 mg and 1 g, which is

the full scope of the extremely broad claim for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claim, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is again suggested.

ACTION IS FINAL

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

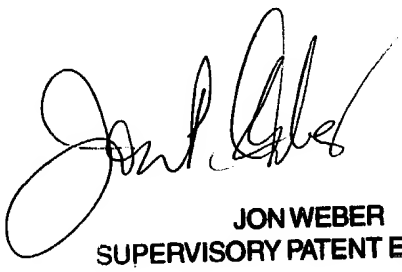
4. Claims 1-5 are allowed and claims 6-13 are rejected.

thousand times) intended to be effective for the claimed purpose of treatment or prevention of the various disorders as encompassed in the claims would be effective and under what conditions. Secondly, the Examiner has clearly shown in the previous Office Action mailed 4/20/04 and as discussed above that without guidance through working example(s), one of ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 6-13, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above. Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER
SUPERVISORY PATENT EXAMINER

AAM Mohamed/AAM
October 14, 2004